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#33

Continuation-in-part application of Vincent BRYAN and Alex KUNZLER

Appln. No. 08/944,234

Group Art Unit: 3731

Examiner: L. Ngo

Filed: October 6, 1997

For: DRILL HEAD FOR USE IN PLACING A VERTEBRAL BODY DISC DEVICE

**REQUEST FOR AN INTERFERENCE WITH
A PATENT UNDER 37 C.F.R. §1.607**

Assistant Commission For Patents
Washington, D.C. 20231

Sir:

I. 37 C.F.R. §1.607(a)(1)

The patent is U.S. Patent No. 6,083,228 issued July 4, 2000, and naming Gary K. Michelson as the inventor.

II. 37 C.F.R. §1.607(a)(2)

Applicants propose the following count, which is in the format approved by the Commissioner in *Orikasa v. Oonishi*, 10 U.S.P.Q.2d 1999, 2003 (Comm'r Pat. & Tr. 1990), and *Davis v. Uke*, 27 U.S.P.Q. 2d 1180, 1188 (Comm'r Pat. & Tr. 1993):

Count 1:

Claim 1 or Claim 29 or Claim 63 of U.S. Patent No. 6,083,228 (Michelson)

OR

Claim 25 or Claim 41 or Claim 62

added by preliminary amendment to the present Bryan et al. CPA application.

Pursuant to the Commissioner's opinion in Orikasa, it is appropriate to use a count of this type where the recited claims are in different statutory classes so long as the subject matter recited in the various claims is not patentably distinct.

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III. 37 C.F.R. §1.607(a)(3)

All 162 claims in the Michelson patent correspond to the proposed count.

IV. 37 C.F.R. §1.607(a)(4)

Claims 25-125 presented in the preliminary amendment submitted herewith in Applicant's present CPA application correspond to the proposed count.

V. 37 C.F.R. §1.607(a)(5)

The terms of the application claims identified as corresponding to the proposed count and not previously in the application are applied to the disclosure of the application as follows:

25. A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising:

page 4, lines 1-3

(a) an elongated shaft portion;

Fig. 2: 40

(b) a housing disposed at the distal end of said elongated shaft portion;

Figs. 1, 2: 31

(c) a drive means;

Fig. 2: 24

(d) a drive source operably connected to said drive means; and

Fig. 2: 61

(e) a form cutter mountable on said housing and movable by said drive means, wherein:

Fig. 2: 29
page 6, lines 11-13

(f) said form cutter has at least one milling surface selected to create a surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means.

Fig. 2: 42
page 5, lines 10-14

26. The device of claim 25, wherein said housing is fixedly connected to said elongated shaft

Fig. 2
Page 5, lines 8-9

portion.

27. The device of claim 25, wherein:

- (a) said housing includes a shaft support; and
- (b) said form cutter includes a form cutter shaft configured to fit within said shaft support of said housing.

Fig. 2: 37

Fig. 2: 51
Page 5, lines 19-21

28. The device of claim 25, wherein said at least one milling surface is configured such that it is operated in a plane generally parallel to the surface contour formed in one of the adjacent vertebral bodies as said form cutter is moved by said drive means.

Page 7, lines 3-6
Fig. 2;
Page 5, lines 5-7 and
USP 5,674,296, Figs. 2, 3
(incorporated by reference)

29. The device of claim 25, wherein said housing includes:

- (a) an upstanding wall;
- (b) a shaft support; and
- (c) a slot configured through said upstanding wall through which said drive means is operatively coupled to said form cutter.

Fig. 2: 35

Fig. 2: 37

Fig. 2
Page 6, lines 11-15;
Fig. 3
Page 7, lines 13-18

30. The device of claim 25 including drive means that operatively couples said form cutter to said drive source.

Fig. 2: 24
Page 6, lines 19-20

31. The device of claim 30, wherein:

- (a) said drive means comprises a drive shaft having a proximal end and a distal end;
- (b) said drive shaft is adapted to be received in

Fig. 2: 54

Fig. 2

said elongated shaft portion;

Page 5, lines 8-10

(c) the distal end of said drive shaft is operatively coupled to said form cutter to move said form cutter; and

Fig. 2
Page 6, lines 11-18

(d) the proximal end of said drive shaft is operatively coupled to said drive source.

Fig. 2
Page 6, lines 11-13

32. The device of claim 25, wherein said drive means is disposed at least in part in said elongated shaft portion.

Fig. 2
Page 5, lines 8-10

33. The device of claim 25, wherein:

(a) the device includes a drive shaft disposed within said elongated shaft portion;

Fig. 2: 54, 40;
Page 5, lines 8-10

(b) said drive shaft is rotatably driven by said drive source;

Page 5, lines 11-13, 16-18

(c) said drive shaft has a gear at its distal end; and

Fig 2: 59

(d) said gear is configured to mate with corresponding teeth on said form cutter.

Fig. 2: 57 & 59
Page 6, lines 13-18

34. The device of claim 33, wherein:

(a) said form cutter includes at least one top milling surface and a bottom surface;

Fig. 2: 42, 47

(b) said bottom surface is provided with a beveled gearing surface;

Fig. 2: 47, 49
Page 6, lines 15-16

(c) said beveled gearing surface engages teeth on said gear; and

Fig. 2: 49, 59
Page 6, lines 16-18

(d) said gear and said beveled gearing surface cooperate to rotate said form cutter as said drive shaft is rotatably driven.

Fig. 2
Page 6, lines 16-18

35. The device of claim 25, wherein said form cutter is driven in rotary motion by said drive means.

Page 6, lines 16-18

36. The device of claim 25, wherein said form cutter comprises at least two milling surfaces for simultaneously creating at least two predetermined surface contours on an end plate of one of the adjacent vertebral bodies.

Fig. 2: 42, 44
Page 5, lines 10-16

37. The device of claim 25, wherein:

(a) said housing includes a smooth surface formed on a side of said housing opposite said milling surface; and

Fig. 2

(b) said smooth surface is configured to allow a surgeon to increase the pressure of said milling surface against the one of the adjacent vertebral bodies.

Fig. 2

38. The device of claim 25, wherein said form cutter includes a leading edge configured as a bone cutting surface.

Fig. 2: 44

39. The device of claim 36, wherein at least one of said at least two milling surfaces of said form is convex.

Fig. 2: 42
page 5, lines 10-14

40. The device of claim 36, wherein at least one of said at least two milling surfaces of said form cutter is tapered outwardly from a front surface of said form cutter.

Fig. 2: 44
Page 5, line 15

41. A form cutter for preparing a space between adjacent vertebral bodies to receive an insert, said form cutter having:

Page 4, lines 10-12

(a) at least one milling surface and being mountable on a device capable of moving said form cutter to cause said at least one milling surface to create at least one surface having a predetermined contour in an end plate of at least one of the adjacent vertebral bodies,

Figs. 1 & 2

(b) said at least one milling surface having a width selected to substantially match the overall width of the insert to be received between the adjacent vertebral bodies,

Page 5, lines 10-14
U.S. Patent 5,674,296,
incorporated by reference

(c) said at least one milling surface being configured and oriented such that it is generally parallel to the surface having a predetermined contour created in the end plate of the adjacent vertebral body when in use.

Page 7, lines 3-6
Page 5, lines 5-7
U.S. Patent 5,674,296,
incorporated by reference
Figs. 2, 3

42. The form cutter of claim 41, wherein said form cutter has a top surface and a bottom surface.

Fig. 2: 29, 47

43. The form cutter of claim 42, wherein at least one of said top surface and said bottom surface is a milling surface.

Fig. 2: 22

44. The form cutter of claim 41, wherein said form cutter has a leading edge configured to cut into the vertebral body as said form cutter is inserted into the spine.

Fig. 2: 44

45. The form cutter of claim 42, wherein at least one of said top surface and said bottom surface of said form cutter comprises a convex surface.

Fig. 2: 42
page 5, lines 10-14

46. The form cutter of claim 42, wherein at least one area of said top surface and said bottom surface of said form cutter is tapered outwardly from the front surface of said form cutter.

Fig. 2: 44
Page 5, line 15

47. A device for preparing a space in a human spine across a disc space and into the end plates of adjacent vertebral bodies to receive an interbody spinal insert, said device comprising:

Page 4, lines 1-3

- (a) an elongated shaft portion;
- (b) a housing disposed at the distal end of said elongated shaft portion;
- (c) a drive means;
- (d) a drive source for powering said drive means;
- (e) a form cutter mountable on said housing;
and
- (f) a coupling means for connecting and imparting motion from said drive means to said form cutter,

Fig. 2: 40

Figs. 1, 2: 31

Fig. 2: 24

Fig. 2: 61

Fig. 2: 29
Page 6, lines 11-13

Fig. 2: 63, 54, 59

wherein:

- (g) said form cutter has at least one broad milling surface selected to remove bone from and create a predetermined surface contour in at least one of the end plates of the adjacent vertebral bodies as said form cutter is moved by said drive

Fig. 2: 42, 44
Page 4, lines 10-13
Page 5, lines 10-14

means; and

(h) said milling surface is configured to substantially match in width and contour a surface of the interbody spinal insert and the predetermined surface contour in at least one of the end plates of the adjacent vertebral bodies.

Page 5, lines 10-14

Page 7, lines 3-6

48. The device of claim 47, wherein:

(a) said drive means moves said form cutter in a plane generally parallel to the predetermined surface contour to be formed in at least one of the end plates of the adjacent vertebral bodies; and

Page 7, lines 3-6

Fig. 2;

Page 5, lines 5-7 and

USP 5,674,296, Figs. 2, 3
(incorporated by reference)

(b) the movement of said form cutter is rotary.

Fig. 2

Page 6, lines 16-18

49. A device for preparing a space to receive an interbody insert within and between the adjacent surfaces of vertebral bodies disposed adjacent a disc space, said device comprising:

Page 4, lines 1-3

(a) an elongated shaft containing at least a portion of a drive means;

Fig. 2: 40, 24

(b) a housing positioned at the distal end of said elongated shaft portion; and

Figs. 1 & 2: 31

(c) a form cutter disposed on said housing and operably connected to said drive means to be driven thereby,

Fig. 2: 24, 29
Page 6, lines 11-13

wherein:

(d) said form cutter has a milling surface;

Fig. 2: 42

(e) said milling surface has a width substantially the same as the width of the insert to be implanted;

Page 5, lines 10-14
U.S. Patent 5,674,296,
Incorporated by reference

(f) said milling surface has a configuration adapted to remove bone from the vertebral bodies to prepare the vertebral bodies to receive the insert; and

Page 5, lines 10-14

(g) said milling surface of said form cutter is configured to be generally parallel to a receiving surface that is formed on one of the vertebral bodies by said device.

Page 7, lines 3-6
Fig. 2;
Page 5, lines 5-7 and
USP 5,674,296, Figs. 2, 3
(incorporated by reference)

50. The device of claim 49, wherein said form cutter includes first and second outwardly facing milling surfaces.

Fig. 2: 42, 44
Page 5, lines 10-12, 15-16

51. The device of claim 49, wherein the width of said milling surface substantially matches the width of the nucleus pulposus of a disc space in which said milling surface is inserted.

USP 5,674,296, Figs. 1, 2, 3
(incorporated by reference)
col. 6, lines 40-46

52. The device of claim 49, wherein said form cutter has at least one milling surface having a convex configuration.

Fig. 2: 42
Page 5, lines 10-14

53. The device of claim 49, wherein:

(a) said form cutter includes outwardly facing first and second milling surfaces; and

Fig. 2: 42, 44
Page 5, lines 10-12, 15-16

(b) said outwardly facing first and second milling surfaces are inclined relative to one another.

Fig. 2: 42, 44
Page 5, lines 10-12, 15-16

54. The device of claim 50, wherein said outwardly facing first and second milling surfaces are inclined with respect to each other.

Fig. 2: 42, 44
Page 5, lines 10-12, 15-16

55. The device of claim 49, wherein said drive means is adapted to produce a rotary movement of said form cutter about an axis generally perpendicular to a longitudinal axis of said elongated shaft portion and a general plane of the vertebral end plate.

Page 7, lines 3-6
Fig. 2;
Page 5, lines 5-7 and
USP 5,674,296, Figs. 2, 3
(incorporated by reference)

56. The device of claim 49, wherein said drive means is powered by a drive source.

Fig. 2: 61
Fig. 3, motor 65
Page 6, line 19 to page 7, line 2

57. The device of claim 49, wherein said housing has a surface opposite said milling surface of said form cutter for bearing against the vertebral body on the opposite side of the disc space.

Figs. 1, 2, 3

58. The device of claim 57, wherein said bearing surface is smooth.

Figs. 1, 2, 3

59. The device of claim 49, wherein said device is sterilizable for use in surgery.

Page 5, lines 10-14
(Sterilization inherent in instrument for surgery)

60. The device of claim 49, wherein said form cutter is detachable from said housing.

Page 5, line 19 to page 6, line 2

61. The device of claim 49, including a rotatable drive shaft disposed within said elongated shaft portion, said rotatable drive shaft being operably connected to said drive means and to said

Fig. 2: 54, 40
Page 6, lines 11-18

form cutter.

62. A method for preparing the disc space between adjacent vertebrae of a human spine to receive an insert therebetween, said method being performed with a device having a movable form cutter with a milling surface that has a width substantially the same as the width of the insert to be implanted between the adjacent vertebrae, said method comprising the steps of:

Page 5, lines 10-14
U.S. Patent 5,674,296,
incorporated by reference

(a) activating the device to cause the milling surface to move;

Page 6, lines 16-18

(b) inserting the milling surface into the space between the adjacent vertebrae;

Page 6, lines 3-10

(c) contacting the milling surface of the form cutter against at least one of the adjacent vertebrae to remove bone from the end plate of the vertebra that lies adjacent the disc space to form a surface of that vertebra, the surface of that vertebra having a contour that substantially matches the contour of a surface of the insert to be implanted and that substantially matches the contour of the milling surface; and

Page 5, lines 10-15

(d) moving the milling surface of the form cutter in a rotary fashion relative to said device in a plane generally parallel to the surface contour to be formed in at least one of the adjacent vertebral bodies.

Page 6, lines 16-18
Page 7, lines 3-6
Fig. 2;
Page 5, lines 5-7 and
USP 5,674,296, Figs. 2, 3
(incorporated by reference)

63. The method of claim 62, wherein the form cutter includes first and second outwardly facing

Fig. 2: 42, 44
Page 5, lines 10-12, 15-16

milling surfaces.

64. The method of claim 63, wherein the device is not activated until after the milling surface has been inserted into the space between the adjacent vertebrae.

Page 6, lines 3-10
Insert shape formed by form cutter 29
as illustrated in U.S. Patent 5,674,296,
incorporated by reference
Figs. 1, 2

65. The method of claim 62, including the steps of:

- (a) measuring the width of the desired space to be formed between the adjacent vertebrae; and
- (b) selecting a form cutter and corresponding milling surface that matches the measured width.

U.S. Patent 5,674,296,
incorporated by reference
col. 6, lines 16-39
Page 5, lines 3-6

66. The method of claim 63, including the further steps of:

- (a) removing the milling surface from the disc space after completing the contacting step; and then
- (b) positioning an insert into the space created between the adjacent vertebrae.

Page 5, lines 10-14
(inherent to remove surgical instrument
following surgical procedure)
Page 5, lines 10-14

67. A device for preparing a space in the human spine to receive an insert between adjacent vertebral bodies, said device comprising:

page 4, lines 1-3

- (a) an elongated shaft portion;
- (b) a housing disposed at the distal end of said elongated shaft portion;
- (c) a drive means;
- (d) a drive source operably connected to said drive means;
- (e) a form cutter mountable on said housing

Fig. 2: 40

Figs. 1, 2: 31

Fig. 2: 24

Fig. 2: 61

Fig. 2: 29

and movable by said drive means;

page 6, lines 11-13

(f) said form cutter having at least one milling surface selected to create a predetermined surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means;

Fig. 2: 42
page 5, lines 10-14

(g) said drive means including a drive shaft disposed within said elongated shaft portion;

Fig 2: 54
Page 5, lines 5-10

(h) said drive shaft being rotatably driven by said drive means; and

Page 5, lines 11-13, 16-18

(i) said drive shaft being operably coupled to said form cutter.

Fig. 2: 24
Page 6, lines 19-20

68. The device of claim 67, wherein

(a) said form cutter includes first and second milling surfaces;

Fig. 2: 42, 44

(b) said drive shaft has a gear at its distal end

Fig. 2: 59

(c) said gear is configured to engage corresponding teeth on said form cutter;

Fig. 2: 57 & 59
Page 6, lines 13-18

(d) said gear and said teeth are configured such that said form cutter having said first and second milling surfaces is rotated as said drive shaft is rotated by said drive means.

Fig. 2
Page 6, lines 16-18

69. The device of claim 67, wherein said housing is fixedly connected to said elongated shaft portion.

Fig. 2
Page 5, lines 8-9

70. The device of claim 67, wherein:

(a) said housing includes a shaft support; and

Fig. 2: 37

(b) said form cutter includes a form cutter shaft configured to fit within said shaft support of said

Fig. 2: 51
Page 5, lines 19-21

housing.

71. The device of claim 67, wherein said at least one milling surface is configured such that it is operated in a plane generally parallel to the surface contour formed in one of the adjacent vertebral bodies as said form cutter is moved by said drive means.

Page 7, lines 3-6
Fig. 2;
Page 5, lines 5-7 and
USP 5,674,296, Figs. 2, 3
(incorporated by reference)

72. The device of claim 67, wherein said housing includes:

- (a) an upstanding wall;
- (b) a shaft support; and
- (c) a slot configured through said upstanding wall through which said drive means is operatively coupled to said form cutter.

Fig. 2: 35
Fig. 2: 37
Fig. 2
Page 6, lines 11-15;
Fig. 3
Page 7, lines 13-18

73. The device of claim 67 including drive means that operatively couples said form cutter to said drive source.

Fig. 2: 24
Page 6, lines 19-20

74. The device of claim 73, wherein:

- (a) said drive means comprises a drive shaft having a proximal end and a distal end;
- (b) said drive shaft is adapted to be received in said elongated shaft portion;
- (c) the distal end of said drive shaft is operatively coupled to said form cutter to move said form cutter; and
- (d) the proximal end of said drive shaft is

Fig. 2: 54

Fig. 2
Page 5, lines 8-10

Fig. 2
Page 6, lines 11-18

Fig. 2

operatively coupled to said drive source.

Page 6, lines 11-13

75. The device of claim 67, wherein said drive means is disposed at least in part in said elongated shaft portion.

Fig. 2
Page 5, lines 8-10

76. The device of claim 67, wherein said form cutter is driven in rotary motion by said drive means.

Page 6, lines 16-18

77. The device of claim 67, wherein said form cutter comprises at least two milling surfaces for simultaneously creating at least two predetermined surface contours on an end plate of one of the adjacent vertebral bodies.

Fig. 2: 42, 44
Page 5, lines 10-16

78. The device of claim 67, wherein:

(a) said housing includes a smooth surface formed on a side of said housing opposite said milling surface; and

Fig. 2

(b) said smooth surface is configured to allow a surgeon to increase the pressure of said milling surface against the one of the adjacent vertebral bodies.

Fig. 2

79. The device of claim 67, wherein said form cutter includes a leading edge configured as a bone cutting surface.

Fig. 2: 44

80. The device of claim 68, wherein at least one of said at least two milling surfaces of said form is

Fig. 2: 42
page 5, lines 10-14

convex.

81. The device of claim 68, wherein at least one of said at least two milling surfaces of said form cutter is tapered outwardly from a front surface of said form cutter.

Fig. 2: 44
Page 5, line 15

82. A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising:

Page 4, lines 1-3

- (a) an elongated shaft portion;
- (b) a housing disposed at the distal end of said elongated shaft portion;
- (c) a drive means;
- (d) a drive source operably connected to said drive means;
- (e) a form cutter mountable on said housing and movable by said drive means, wherein:
- (f) said form cutter has at least one milling surface selected to create a predetermined surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means; and
- (g) said housing has a smooth surface formed on a side of said housing opposite said milling surface.

Fig. 2: 40

Figs. 1, 2: 31

Fig. 2: 24

Fig. 2: 61

Fig. 2: 29
page 6, lines 11-13

Fig. 2: 42
page 5, lines 10-14

Fig. 2

83. The device of claim 82, wherein said housing is fixedly connected to said elongated shaft portion.

Fig. 2
Page 5, lines 8-9

84. The device of claim 82, wherein:

- (a) said housing includes a shaft support; and
- (b) said form cutter includes a form cutter shaft configured to fit within said shaft support of said housing.

Fig. 2: 37

Fig. 2: 51
Page 5, lines 19-21

85. The device of claim 82, wherein said at least one milling surface is configured such that it is operated in a plane generally parallel to the surface contour formed in one of the adjacent vertebral bodies as said form cutter is moved by said drive means.

Page 7, lines 3-6
Fig. 2;
Page 5, lines 5-7 and
USP 5,674,296, Figs. 2, 3
(incorporated by reference)

86. The device of claim 82, wherein said housing includes:

- (a) an upstanding wall;
- (b) a shaft support; and
- (c) a slot configured through said upstanding wall through which said drive means is operatively coupled to said form cutter.

Fig. 2: 35

Fig. 2: 37

Fig. 2
Page 6, lines 11-15;
Fig. 3
Page 7, lines 13-18

87. The device of claim 82 including drive means that operatively couples said form cutter to said drive source.

Fig. 2: 24
Page 6, lines 19-20

88. The device of claim 87, wherein:

- (a) said drive means comprises a drive shaft having a proximal end and a distal end;
- (b) said drive shaft is adapted to be received in said elongated shaft portion;
- (c) the distal end of said drive shaft is

Fig. 2: 54

Fig. 2
Page 5, lines 8-10

Fig. 2

operatively coupled to said form cutter to move said form cutter; and

Page 6, lines 11-18

(d) the proximal end of said drive shaft is operatively coupled to said drive source.

Fig. 2
Page 6, lines 11-13

89. The device of claim 82, wherein said drive means is disposed at least in part in said elongated shaft portion.

Fig. 2
Page 5, lines 8-10

90. The device of claim 82, wherein:

(a) the device includes a drive shaft disposed within said elongated shaft portion;

Fig. 2: 54, 40;
Page 5, lines 8-10

(b) said drive shaft is rotatably driven by said drive source;

Page 5, lines 11-13, 16-18

(c) said drive shaft has a gear at its distal end; and

Fig 2: 59

(d) said gear is configured to mate with corresponding teeth on said form cutter.

Fig. 2: 57 & 59
Page 6, lines 13-18

91. The device of claim 90, wherein:

(a) said form cutter has at least one top milling surface and a bottom surface;

Fig. 2: 42, 47

(b) said bottom surface is provided with a beveled gearing surface;

Fig. 2: 47, 49
Page 6, lines 15-16

(c) said beveled gearing surface engages teeth on said gear; and

Fig. 2: 49, 59
Page 6, lines 16-18

(d) said gear and said beveled gearing surface cooperate to rotate said form cutter as said drive shaft is rotatably driven by said drive means.

Fig. 2
Page 6, lines 16-18

92. The device of claim 82, wherein said form

Page 6, lines 16-18

cutter is driven in rotary motion by said drive means.

93. The device of claim 82, wherein said form cutter comprises at least two milling surfaces for simultaneously creating at least two predetermined surface contours on an end plate of one of the adjacent vertebral bodies.

Fig. 2: 42, 44
Page 5, lines 10-16

94. The device of claim 93, wherein said form cutter includes a leading edge configured as a bone cutting surface.

Fig. 2: 44

95. The device of claim 93, wherein at least one of said at least two milling surfaces of said form is convex.

Fig. 2: 42
page 5, lines 10-14

96. The device of claim 93, wherein at least one of said at least two milling surfaces of said form cutter is tapered outwardly from a front surface of said form cutter.

Fig. 2: 44
Page 5, line 15

97. A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising:

Page 4, lines 1-3

- (a) an elongated shaft portion;
- (b) a housing disposed at the distal end of said elongated shaft portion;
- (c) a drive means;
- (d) a drive source operably connected to said drive means; and

Fig. 2: 40

Figs. 1, 2: 31

Fig. 2: 24

Fig. 2: 61

(e) a form cutter mountable on said housing and movable by said drive means, wherein:

Fig. 2: 29
Page 6, lines 11-13

(f) said form cutter has at least one milling surface selected to create a predetermined surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means.

Fig. 2: 42
Page 5, lines 10-14

98. The device of claim 97, wherein said form cutter has at least two milling surfaces.

Fig. 2: 42, 44

99. The device of claim 98, wherein said form cutter includes a leading edge configured as a bone cutting surface.

Fig. 2: 44

100. The device of claim 97, wherein said housing is fixedly connected to said elongated shaft portion.

Fig. 2
Page 5, lines 8-9

101. The device of claim 97, wherein:

(a) said housing includes a shaft support; and
(b) said form cutter includes a form cutter shaft configured to fit within said shaft support of said housing.

Fig. 2: 37

Fig. 2: 51
Page 5, lines 19-21

102. The device of claim 97, wherein said at least one milling surface is configured such that it is operated in a plane generally parallel to the surface contour formed in one of the adjacent vertebral bodies as said form cutter is moved by said drive means.

Page 7, lines 3-6
Fig. 2;
Page 5, lines 5-7 and
USP 5,674,296, Figs. 2, 3
(incorporated by reference)

103. The device of claim 97, wherein said housing includes:

- (a) an upstanding wall;
- (b) a shaft support; and
- (c) a slot configured through said upstanding wall through which said drive means is operatively coupled to said form cutter.

Fig. 2: 35

Fig. 2: 37

Fig. 2
Page 6, lines 11-15;
Fig. 3
Page 7, lines 13-18

104. The device of claim 97 including drive means that operatively couples said form cutter to said drive source.

Fig. 2: 24
Page 6, lines 19-20

105. The device of claim 104, wherein:

- (a) said drive means comprises a drive shaft having a proximal end and a distal end;
- (b) said drive shaft is adapted to be received in said elongated shaft portion;
- (c) the distal end of said drive shaft is operatively coupled to said form cutter to move said form cutter; and
- (d) the proximal end of said drive shaft is operatively coupled to said drive source.

Fig. 2: 54

Fig. 2
Page 5, lines 8-10

Fig. 2
Page 6, lines 11-18

Fig. 2
Page 6, lines 11-13

106. The device of claim 97, wherein said drive means is disposed at least in part in said elongated shaft portion.

Fig. 2
Page 5, lines 8-10

107. The device of claim 97, wherein:

- (a) the device includes a drive shaft disposed within said elongated shaft portion;
- (b) said drive shaft is rotatably driven by said

Fig. 2: 54, 40;
Page 5, lines 8-10
Page 5, lines 11-13, 16-18

drive source;

(c) said drive shaft has a gear at its distal end;
and

(d) said gear is configured to mate with
corresponding teeth on said form cutter.

Fig 2: 59

Fig. 2: 57 & 59
Page 6, lines 13-18

108. The device of claim 107, wherein:

(a) said form cutter has at least one top face
having first and second milling surfaces and a
bottom surface;

Fig. 2: 42, 47

(b) said bottom surface is provided with a
beveled gearing surface;

Fig. 2: 47, 49
Page 6, lines 15-16

(c) said beveled gearing surface engages teeth
on said gear; and

Fig. 2: 49, 59
Page 6, lines 16-18

(d) said gear and said beveled gearing surface
cooperate to rotate said form cutter as said drive
shaft is rotatably driven by said drive means.

Fig. 2
Page 6, lines 16-18

109. The device of claim 97, wherein said form
cutter is driven in rotary motion by said drive
means.

Page 6, lines 16-18

110. The device of claim 97, wherein said form
cutter comprises at least two milling surfaces for
simultaneously creating at least two predetermined
surface contours on an end plate of one of the
adjacent vertebral bodies.

Fig. 2: 42, 44
Page 5, lines 10-16

111. The device of claim 97, wherein said
housing includes a smooth surface formed on a side
of said housing opposite said milling surface, said

Fig. 2

smooth surface being configured to allow a surgeon to increase the pressure of said milling surface against the one of the adjacent vertebral bodies.

112. The device of claim 97, wherein at least one of said at least two milling surfaces of said form is convex.

Fig. 2: 42
page 5, lines 10-14

113. The device of claim 97, wherein at least one of said at least two milling surfaces of said form cutter is tapered outwardly from a front surface of said form cutter.

Fig. 2: 44
Page 5, line 15

114. A form cutter for preparing a space between adjacent vertebral bodies to receive an insert, said form cutter having:

Page 4, lines 10-12

(a) at least one milling surface and being mountable on a device capable of moving said form cutter to cause said at least one milling surface to create at least one surface having a predetermined contour in an end plate of at least one of the adjacent vertebral bodies;

Figs. 1 & 2

(b) said at least one milling surface having a width selected to substantially match the overall width of the insert to be received between the adjacent vertebral bodies;

Page 5, lines 10-14
U.S. Patent 5,674,296,
Incorporated by reference

(c) said at least one milling surface having a perimeter that is at least in part arcuate; and

Figs. 1 & 2: 29

(d) said form cutter having a leading edge configured to cut into the vertebral body as said form cutter is inserted into the spine.

Fig. 2: 44

115. The form cutter of claim 114, wherein said form cutter has a top surface and a bottom surface.

Fig. 2: 29, 47

116. The form cutter of claim 115, wherein at least one of said top surface and said bottom surface comprises at least one milling surface.

Fig. 2: 22

117. The form cutter of claim 115, wherein at least one of said top surface and said bottom surface of said form cutter comprises at least one milling surface that is convex.

Fig. 2: 42
Page 5, lines 10-14

118. The form cutter of claim 115, wherein at least one of said top surface and said bottom surface of said form cutter comprises at least one milling surface that is tapered outwardly from the front surface of said form cutter.

Fig. 2: 44
Page 5, line 15

119. The form cutter of claim 114, said at least one milling surface being configured and oriented such that it is generally parallel to the surface having a predetermined contour created in the end plate of the at least one of the adjacent vertebral bodies when in use.

Page 7, lines 3-6
Page 5, lines 5-7
U.S. Patent 5,674,296,
Incorporated by reference
Figs. 2, 3

120. A device for preparing a space in a human spine across a disc space and into the end plates of adjacent vertebral bodies to receive an interbody spinal insert, comprising:

Page 4, lines 1-3

(a) an elongated shaft portion;

Fig. 2: 40

(b) a housing disposed at the distal end of said elongated shaft portion;

Figs. 1, 2: 31

(c) a drive means;

Fig. 2: 24

(d) a drive source operably connected to said drive means;

Fig. 2: 61

(e) a form cutter mountable on said housing and movable by said drive means;

Fig. 2: 29
page 6, lines 11-13

(f) drive means that operatively couples said form cutter to said drive source to move said form cutter;

Fig. 2: 24
Page 6, lines 19-20

(g) said form cutter having a broad milling surface selected to remove bone from and create a predetermined surface contour in at least one of the end plates of the adjacent vertebral bodies as said form cutter is moved by said drive means in a plane generally parallel to the predetermined surface contour to be formed in said vertebral body;

Fig. 2: 42
Page 5, lines 10-14

(h) said form cutter being driven in rotary motion by said drive means; and

Page 7, lines 3-6
Fig. 2;
Page 5, lines 5-7 and
USP 5,674,296, Figs. 2, 3
(incorporated by reference)

(i) said milling surface being configured to substantially match in width and contour a surface of said interbody spinal insert.

Page 6, lines 16-18

Page 5, lines 10-14
Page 7, lines 3-6

121. A form cutter for preparing a space between adjacent vertebral bodies to receive an insert, said form cutter having:

Page 4, lines 10-12

(a) at least one top milling surface for removing bone;

Fig. 2: 42, 44

(b) A bottom surface opposite said at least one top milling surface adapted to mount on a device capable of moving said form cutter;

Fig. 2: 29, 47

(c) said at least one top milling surface of said moving form cutter being capable of removing bone from an end plate of at least one of said adjacent vertebral bodies to create at least one surface in said end plate having a predetermined contour;

Figs. 1 & 2
Page 4, lines 10-13
Page 5, lines 7-14

(d) said at least one top milling surface having a width selected to substantially match the overall width of said insert to be received between said adjacent vertebral bodies; and

Page 5, lines 10-14
U.S. Patent 5,674,296,
Incorporated by reference

(e) said form cutter having a leading edge configured to cut into the vertebral body as said form cutter is inserted into the spine.

Fig. 2: 44

122. The form cutter of claim 121, wherein said top surface of said form cutter is capable of milling bone.

Page 7, lines 4-6

123. The form cutter of claim 121, wherein at least one milling surface provided on said top surface of said form cutter is convex.

Fig. 2: 42
Page 5, lines 10-14

124. The form cutter of claim 121, wherein at least one milling surface provided on said top surface of said form cutter is tapered outwardly from the front surface of said form cutter.

Fig. 2: 44
Page 5, line 15

125. The form cutter of claim 121, wherein said at least one milling surface is configured and oriented such that it is generally parallel to the surface formed in said end plate of said vertebral

Page 7, lines 3-6
Page 5, lines 5-7
U.S. Patent 5,674,296,
Incorporated by reference
Figs. 2, 3

body when in use.

VI. 37 C.F.R. §1.607(a)(6)

The requirements of 35 U.S.C. § 135(b) are met because U.S. Patent 6,083,228 to Michelson issued on July 4, 2000.

Claims meet the requirement of 35 U.S.C. § 135(b) if they are present in an application on the anniversary date of the issuance of a patent, which in the present case is July 4, 2001. MPEP § 2307; *Switzer v. Sockman*, 333 F.2d 935, 142 U.S.P.Q. 226 (CCPA 1964).

Because July 4, 2001 was a Federal holiday in the District of Columbia, the time for presenting the present claims is extended until July 5, 2001. Pursuant to 37 C.F.R. §1.7(a):

When the day, or the last day fixed by statute or by or under this part for taking any action or paying any fee in the United States Patent and Trademark Office falls on Saturday, Sunday, or on a Federal holiday within the District of Columbia, the action may be taken, or the fee paid, on the next succeeding business day which is not a Saturday, Sunday, or a Federal holiday.

For this reason, this request under 37 C.F.R. §1.607(a) meets the timeliness requirement of 35 U.S.C. § 135(b).

VII. REQUEST FOR THE BENEFIT OF THE FILING DATES OF APPLICANTS' PRIORITY APPLICATIONS

Applicants claim priority under 35 U.S.C. § 120 based on application S.N. 08/944,234, which was filed on October 6, 1997. Applicants are entitled to the benefit of the filing dates of their earlier filed application for interference purposes if a count reads on at least one embodiment adequately disclosed in the earlier application.¹

Applicants respectfully submit that at least one embodiment encompassed by the proposed count is adequately disclosed by their prior application, because the present

¹ *Weil v. Fritz*, 572 F.2d 856, 865-66 n.16, 196 U.S.P.Q. 600, 608 n.16 (CCPA 1978).

application and all intervening applications were Continued Prosecution Applications under 37 C.F.R. §1.53(d).


Applicants respectfully submit that it is manifest that their originally filed application fully and adequately discloses numerous embodiments within the scope of the proposed count, and fully supports newly-presented claims 25 to 125 under 35 U.S.C. § 120, as shown by application Figs. 1, 2, and 3.

VIII. 37 C.F.R. §1.608

37 C.F.R. §1.608 does not apply, because the October 6, 1997, effective filing date of this application precedes the June 9, 1998 effective filing date of the Michelson patent.

For the foregoing reasons, Applicants respectfully submit that an interference should be declared, and that the party Bryan et al. should be the senior party in the requested interference.

Respectfully submitted,



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